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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/409,800	09/30/1999	FREDERICK R. BLATTNER	960296.95939	5901

26734 7590 12/11/2001

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EXAMINER

EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1655

14

DATE MAILED: 12/11/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/409,800

Applicant(s)

BLATTNER ET AL.

Examiner

Juliet C Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 9-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14. 6) ☐ Other: .

DETAILED ACTION

Sequence Rules

1. The paper copy of the sequence listing and the CRF in this case are proper and have been entered.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4, drawn to polynucleotide sequences from the pMT1 plasmid found in *Yersinia pestis*, classified in class 536, subclass 23.1.
 - II. Claims 5-8, drawn to polynucleotide sequences from the pCD1 plasmid found in *Yersinia pestis*, classified in class 536, subclass 23.1.
 - III. Claims 9-11, drawn to polynucleotide sequences from the pPCP1 plasmid found in *Yersinia pestis*, classified in class 536, subclass 23.1.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple open reading frames, and a further restriction is applied to each Group. Applicants are required to further elect a single nucleic acid sequence for examination. Specifically, applicant must elect for examination one of the following: ORF4, ORF17, ORF18, ORF21, ORF72, ORF74a, ORF42, ORF43, ORF44, ORF5, ORF59, ORF60, ORF61, ORF73, ORF74, ORF84, ORF85, ORF Y004, ORF Y005, or ORF Y007.

3. These groups are all separate and distinct from one another because they are drawn to unique and distinct nucleic acid sequences. The sequences are patentably distinct because they are unrelated sequences with different structures and functions. They have unrelated nucleic acid

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sequences and encode unrelated polypeptides. A search of one does not overlap with a search for the other.

4. It is noted that claims 4 and 8 are generic to the groups I and II, respectively. These claims will be examined as appropriate according to applicant's election. If applicant elects an ORF that is encompassed within group I, then claim 4 will be examined. If applicant elects an ORF that is encompassed within group II then claim 8 will be examined.

5. Because these inventions are distinct for the reasons given above and recognized divergent subject matter and because inventions I-III require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Nicholas Seay on 12/3/01 a provisional election was made with traverse to prosecute the invention of group III, the Y004 open reading frame, claims 9-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-8, and 9-11 with respect to ORF Y005 and Y007 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that the elected claims contain non-elected subject matter. Prior to allowance, amendment of the claims to exclude non-elected subject matter is required.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

9. The information disclosure statement filed 3/3/00 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The reference Sodeine *et al.* in Science 258:1004-1007 (1992) was not provided. This reference has been lined through. The 1449 was signed but this particular reference was lined through.
10. The Brubaker *et al.* reference (C.T. in Microbiology) was lined through because no date was provided. This reference was considered, but if Applicant's desires that this reference appear on the cover of any eventual patent, a new 1449 which complies with all appropriate rules must be submitted listing this reference.

Specification

11. The disclosure is objected to because of the following informalities:
- (A) At page 1, line 7 there is a blank.
 - (B) Table 4 is very difficult to read because the columns are not properly lined up.

Further, it is not clear what information is contained in each column (see page 37).

Appropriate correction is required.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (i.e. page 15 lines 22 and 33). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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13. Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9-11 are indefinite because the designation Y004 is arbitrary. The instantly disclosed polynucleotide could be identified by some other arbitrary name, or the name Y004 could be arbitrarily used to designate another polynucleotide. This rejection may be overcome by providing descriptive characterization of the claimed polynucleotide, for example by using a sequence identifier.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 9-11 encompass subject matter which is non-elected. This rejection is written only with respect to the elected invention, that is open reading frame Y004.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to an isolated polynucleotide sequence that is Y004 as found in plasmid pPCP1 found in *Yersinia pestis*. The specification teaches a single species of Y004, namely nucleotides 2389-2826 of SEQ ID NO: 3. Thus, applicant has express possession of only one species in a genus which comprises many different possibilities.

As is taught by the specification, this claim encompasses versions of Y004 that are present in any possible strain of *Yersinia pestis*, including allelic variants and different possible forms of the ORF (see specification, page 11, lines 6-10). Within this large genus, no additional species are provided which are Y004 open reading frames, nor does the specification provide any information about the critical regions of Y004 that would help a practitioner identify other open reading frames which are changed but still retain the function of Y004.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only one example of Y004 is described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any Y004 polynucleotides modified by addition, insertion, deletion, substitution or inversion of the disclosed nucleotides 2389-2826 of SEQ ID NO: 3 but retaining the function of Y004 as disclosed herein.

Claim Rejections - 35 USC § 101

16. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

17. Claims 10-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Claims 10-11 encompass subject matter which is non-elected. This rejection is written only with respect to the elected invention, that is open reading frame Y004.

This rejection applies to claims 10-11 when Y004 is interpreted as being a nucleic acid consisting of nucleotides 2389-2826 of SEQ ID NO: 3. The instantly rejected claims are thus drawn to a recombinant DNA construction comprising an open reading frame place under the control of a non-native promoter, wherein the open reading frame is Y004, and host cells transformed with the DNA construct. The specification asserts that the instantly claimed constructs and host cells can be used for expression of the polypeptide encoded by the ORF (p. 12, line 21-page 13, line 3).

The specification teaches the full length sequence of the *Yersinia pestis* pPCP1 plasmid (SEQ ID NO: 3), and further teaches that Y004 is a nucleic acid consisting of nucleotides 2389-2826 of SEQ ID NO: 3 (see Table 4).

Yu *et al.* also teach the full length sequence of the pPCP1 plasmid from *Yersinia pestis* (Journal of Bacteriology, Oct. 1998, p. 5192-5202). Yu *et al.* indicate that the full length disclosure of the plasmid is provided in GenBank Accession AF053945 (p. 5193). Nucleotides 2389-2826 of SEQ ID NO: 3 are identical to nucleotides 3490-3927 of the sequence taught by Hu *et al.* (see attached alignment). These nucleotides are within the region designated by Hu *et*

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al. as the origin of replication on pPCP1 (p. 5193). Thus it is not clear that nucleotides 2389-2826 of SEQ ID NO: 3 comprise an open reading frame.

The specification does not provide any guidance or working examples as to how a recombinant DNA construction comprising Y004 (nucleotides 2389-2826 of SEQ ID NO: 3) and host cells transformed with the DNA construct would be used.

Claims 9-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Rakin *et al.* (Microbiology (1996 Dec) 142 (Pt 12) 3415-24).

Rakin *et al.* teach an isolated polynucleotide sequence encoding a 141 aa pesticin immunity polypeptide (Pim) (figure 2). The instant specification teaches that Y004 encodes the *Y. pestis* pesticin immunity protein (see page 37 of the specification). Thus, the polynucleotide taught by Rakin *et al.* appears to be Y004 polynucleotide. Rakin *et al.* further teach the overexpression of pim under the control of the polymerase T7 promoter (i.e. Y004 under the

control of a non-native promoter) (p. 3416-3417, expression studies). Thus the limitations of claims 9-11 are all met by the teachings of Rakin *et al.*

20. Claim 9 is rejected under 35 U.S.C. 102(a) as being anticipated by Hu *et al.* (Journal of Bacteriology, Oct. 1998, p. 5192-5202).

This rejection applies to claim 9 when it is interpreted to be drawn to an isolated nucleic acid comprising nucleotides 2389-2826 of SEQ ID NO: 3. Hu *et al.* teach the entire sequence of the Y. pestis pPCP1 plasmid. Nucleotides 2389-2826 of SEQ ID NO: 3 are identical to nucleotides 3490-3927 of the sequence taught by Hu *et al.* These nucleotides are within the region designated by Hu *et al.* as the origin of replication on pPCP1.

Conclusion

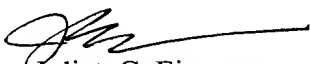
21. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


JEFFREY FREDMAN
PRIMARY EXAMINER


Juliet C. Einsmann
Examiner
Art Unit 1655

December 4, 2001

AF053945

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LOCUS       AF053945      9610 bp    DNA    circular    BCT          06-OCT-1998
DEFINITION  Yersinia pestis plasmid pPCP1, complete plasmid sequence.
ACCESSION   AF053945
VERSION     AF053945.1   GI:2996216
KEYWORDS    .
SOURCE      Yersinia pestis.

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REFERENCE      1 (bases 1 to 9610)
AUTHORS        Hu,P., Elliott,J., McCreedy,P., Skowronski,E., Garnes,J.,
                Kobayashi,A., Brubaker,R.R. and Garcia,E.
TITLE          Structural organization of virulence-associated plasmids of
                Yersinia pestis
JOURNAL        J. Bacteriol. 180 (19), 5192-5202 (1998)
MEDLINE        98422474
REFERENCE      2 (bases 1 to 9610)
AUTHORS        Hu,P., Elliott,J., McCreedy,P., Skowronski,E., Garnes,J.,
                Kobayashi,A., Carrano,A.V., Brubaker,R. and Garcia,E.
TITLE          Direct Submission
JOURNAL        Submitted (16-MAR-1998) Biology and Biotechnology, Lawrence
                Livermore National Lab, L452, 7000 East Ave., Livermore, CA 94550,
                USA

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BASE COUNT	2792 a	2253 c	2098 g	2467 t
ORIGIN				

Query Match 100.0%; Score 438; DB 1; Length 9610;
Best Local Similarity 100.0%; Pred. No. 6.1e-118;
Matches 438; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy	1	gcaaaaaacgaagaccgccagaaaaggccgcgcggaggcgctttttccataggtccgcc	60
Db	3490	GCAAAAAACGAAGACCCCAGAAAAGGCCGCGCGGAGGCGCTTTTCCATAGGCTCCGCC	3549
Qy	61	cccttgacgagcatcacaaaaatcgacgctcaagtcaagggtggcgaaaccgacaggac	120
Db	3550	CCCTTGACGAGCATCACAAAAATCGACGCTCAAGTCAGAGGTGGCGAAACCCGACAGGAC	3609
Qy	121	ttaaagataccaggcggtttccccccggaagctccctcgtgcgctctcctgttccgacct	180
Db	3610	TTAAAGATACCAGGCGTTTCCCCCGGAAGCTCCCTCGTGCCTCTCCTGTTCCGACCCT	3669
Qy	181	gccgcttacggatacctctccgcctttctcccttcgggaagcgtggcgctttctcatag	240
Db	3670	GCCGCTTACCGGATACCTCTCCGCTTTCTCCCTTCGGGAAGCGTGGCGCTTCTCATAG	3729
Qy	241	ctcacgctgttggtatctcagttcgggtgtaggtcggttcgctccaagctgggctgtgtgca	300
Db	3730	CTCACGCTGTTGGTATCTCAGTTCGGGTGAGGTGTTTCGCTCCAAGCTGGGCTGTGTGCA	3789
Qy	301	cgaaccccccgttcagcccgaccactgcgcttatccggtaactatcgctcttgagtccaa	360
Db	3790	CGAACCCCCCGTTCAGCCCGACCACTGCGCCTTATCCGGTAACTATCGTCTTGAGTCCAA	3849
Qy	361	cccggtaagacacgactttacgccactggcagcagccattggtaactgaaaagtggattt	420
Db	3850	CCCGGTAAGACACGACTTTACGCCACTGGCAGCAGCCATTGGTAACGAAAAGTGGATT	3909
Qy	421	agatacgcagaactcttg	438
Db	3910	AGATACGCAGAACTCTTG	3927